

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 74898

ADMINISTRATIVE DOCUMENTS

ANDA APPROVAL SUMMARY

ANDA: 74-898 DRUG PRODUCT: Iopamidol USP
Flexible Container)

FIRM: Abbott DOSAGE FORM: Injection STRENGTH: 41%, 51%,
61%, 76%

CGMP STATEMENT/EIR UPDATE STATUS: EER acceptable as of 5/7/97.

BIO STUDY: OK per Bio review dated 3/27/97 (J.Lee).

VALIDATION - (DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S):
Compendial product. FDA MV not needed.

STABILITY - (ARE CONTAINERS USED IN STUDY IDENTICAL TO THOSE IN
CONTAINER SECTION?):

Three months of accelerated (40°) and up to 12 months of RT (30°C) stability data are provided. Data are within specs. The firm also submitted 7-day accelerated light (AL) stability data generated from both outside and within the overwrap. A significant drop in pH in products without overwrap (ALO) is observed when exposed to accelerated light. Therefore, light protection for the product is recommended.

Containers used in the studies are identical to those in the container section.

LABELING: Satisfactory per labeling review dated 12/11/97 (C.Park).

STERILIZATION VALIDATION (IF APPLICABLE):
Satisfactory per Micro review dated 1/22/97 (K.Muhvich).

SIZE OF BIO BATCH - (FIRM'S SOURCE OF NDS O.K.):

NDS source: OK

Sub-lots:

Conc:	Lot #	Quantity (Theor)
41%	92-834-JE-01	
51%	92-776-JE-01	
61%	05-167-JE	
	05-170-JE	
76%	05-168-JE	
	05-169-JE	

Master lots:

Conc:	Lot #	Quantity (Theor)
41%	92-832-JE**	
51%	92-773-JE**	
61%	05-170-JE	
76%	05-169-JE	

*These sub-lots are split lots between the S (.....) and the Pharmacy Bulk Package (ANDA 74-898).

**Firm indicated that these executed batch records were also submitted in

NDS source: _____

SIZE OF STABILITY BATCHES - (IF DIFFERENT FROM BIO BATCH WERE THEY MANUFACTURED VIA THE SAME PROCESS?) :

Strength	fill	lot #
41%(200 mg I ₂ /mL)	200 mL/200 mL	92-834-JE-01
51%(250 mg I ₂ /mL)	200 mL/200 mL	92-776-JE-01
61%(300 mg I ₂ /mL)	250 mL/250 mL 500 mL/500 mL	05-167-JE 05-170-JE
76%(370 mg I ₂ /mL)	250 mL/250 mL 500 mL/500 mL	05-168-JE 05-169-JE

PROPOSED PRODUCTION BATCH - (MANUFACTURING PROCESS THE SAME AS BIO/STABILITY?) :

Concentrations

41%
51%
61%
76%

Batch sizes: (Theoretical)

Manufacturing processes are essentially the same as those of the biobatches.

REVIEWER:

J. Fan

DATE COMPLETED:

12/17/97

/S/

.sum